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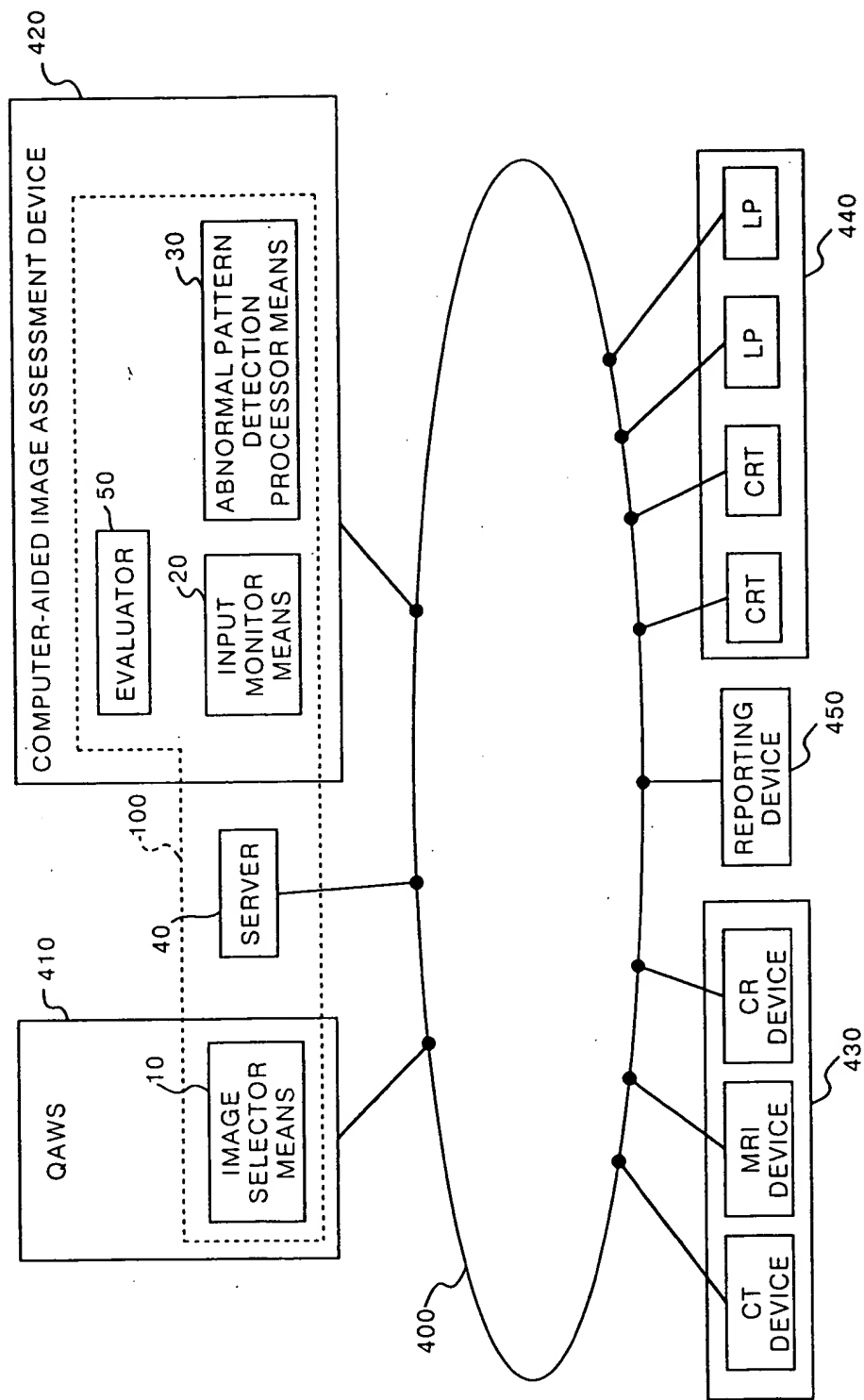


FIG. 1

FIG. 2A

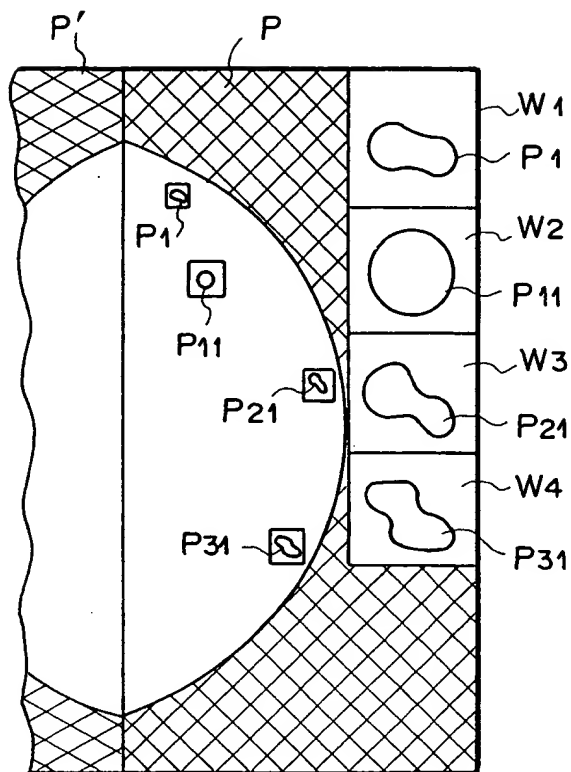
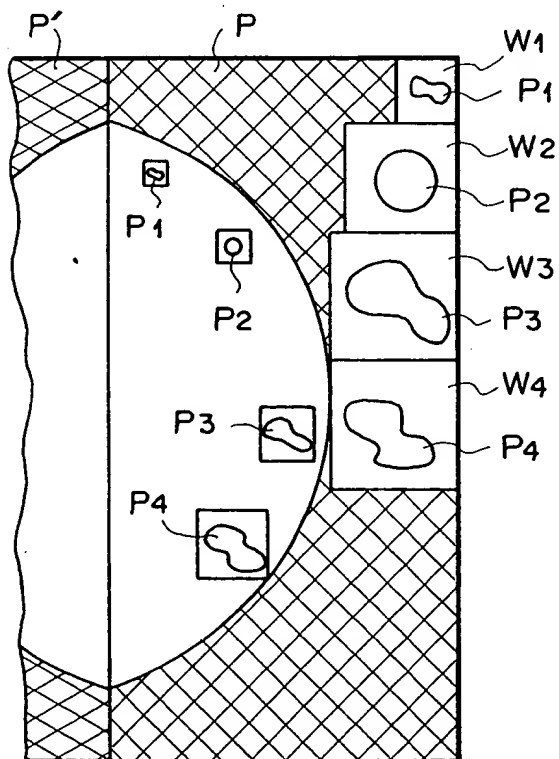


FIG. 2B



# FIG.3

## 【PATIENT INFORMATION】

- ① PATIENT'S NAME, AND PATIENT'S ID
- ② PATIENT'S DATE OF BIRTH (YEARS OLD)
- ③ NAME OF CLINICIAN IN CHARGE
- ④ NAME OF RADIOLOGIST (REPORTER)

## 【BREAST COMPOSITON】

### 1. BRIEF DESCRIPTION OF OVERVIEW OF ENTIRE MAMMOGRAM

- ① FAT (GENERALLY FAT/ADIPOSE)
- ② FIBROGIANDULAR (DISTRIBUTED AT SPARSE DENSITY)
- ③ HETEROGENEOUSLY (HETEROGENEOUSLY THICKSET)
- ④ DENSE

### 2. DETECTION RESULT

#### a-MASS

- a-1 SIZE
- a-2 GEOMETRY/DENSITY
- a-3 EXISTENCE OF CALCIFICATION
- a-4 ASSOCIATED FINDINGS
- a-5 LOCATION

#### b-CALCIFICATIONS

- b-1 GEOMETRY
- b-2 DENSITY
- b-3 ASSOCIATED FINDINGS
- b-4 LOCATION

#### c-ARCHITECTUAL DISTORTION

- c-1 EXISTENCE OF CALCIFICATION
- c-2 ASSOCIATED FINDINGS
- c-3 LOCATION

#### d-SPECIAL CASES

- c-1 EXISTENCE OF CALCIFICATION
- c-2 ASSOCIATED FINDINGS
- c-3 LOCATION

- \* WHEN A PAST IMAGE IS AVAILABLE, RECORD WHAT CHANGE OCCURS.
- \* WHEN THE NIPPLE IS REGARDED AS THE CENTER OF A CLOCK, INDICATE THE DIRECTION WHAT O'CLOCK THE LOATION IS IN.

### 3. DESCRIPTION OF GENERAL IMPRESSION (SUMMARY)

## 【ASSESSMENT CATEGORIES】

IN ACCORDANCE WITH THE FOLLOWING CATEGORIES (WHICH ARE CALLED BI-RADS <sup>TM</sup> CATEGORIES), THE RADIOLOGIST SHALL INDICATE THE RESULT OF PATTERN READING.

CATEGORY 0: NEED ADDITIONAL IMAGE EVALUATION.

CATEGORY 1: NEGATIVE--THERE IS NOTHING TO BE COMMENTED.

CATEGORY 2: BENIGN FINDING.

CATEGORY 3: PROBABLY BENIGN FINDING--NEED SHORT TERM FOLLOW-UP.

CATEGORY 4: THERE IS HIGH POSSIBILITY OF MALIGNANCY. SUSPICIOUS ABNORMALITY--NEED FOR BIOPSY TO BE EXAMINED.

CATEGORY 5: MALIGNANT. HIGH SUGGESTIVE OF MALIGNANCY--AN APPROPRIATE MEASURE TO BE TAKEN.

[illegible]

**DOB : 11 / 5 / 43**

Referring Physician : Ichiroh Fuji

**March 1, 1998**

**Clinical History : Screen.**

**Compared with the prior study of 2 / 1 / 97, there are again scattered fibroglandular densities bilaterally.**

**IMPRESSION :**

**No change from prior examination. No mammographic evidence of malignancy. Yearly mammograms are recommended.**

**BI-RADS <sup>TM</sup> CATEGORY 1 :**

**Negative.**

**Taruh Tokyo  
Radiologist**

FIG.5

SCREENING TEST FOR CANCER

DETACHABLE REFERENCE FOR BIOPSY RESULTS

BIOPSY RESULTS

	POSITIVE (BIOPSY DEMONSTRATED MALIGNANCY)	NEGATIVE (BIOPSY IS BENIGN OR NO CANCER DISCOVERED WITHIN ONE YEAR)
MAMMOGRAM POSITIVE (BI-RADS™ CATEGORIES 0, 4, 5)	TP	FP
MAMMOGRAM NEGATIVE (BI-RADS™ CATEGORIES 1, 2, 3)	FN	TN

SENSITIVITY=TP/(TP+FN)  
SPECIFICITY=TN/(TN+FP)  
PPV=TP/(TP+FP)

# FIG.6

## SAMPLED DATA COLLECTION

BASIC CLINICAL RELEVANT AUDIT, SCREENING CASES ONLY  
FORM A

DATA ITEM	RESULTS
#1 TOTAL SCREENING CASES	
#2 TOTAL SCREENING CASES, ASSESSMENT BI-RADS™ CATEGORY 0, (NEEDS ADDITIONAL IMAGING EVALUATION) AND SCREENING CASES GIVEN ASSESSMENT BI-RADS™ CATEGORY 4 OR 5, WITHOUT FURTHER EVALUATION	
#3 TOTAL SCREENING CASES, <u>FINAL</u> ASSESSMENT BI-RADS™ CATEGORY 4	
#4 TOTAL SCREENING CASES, <u>FINAL</u> ASSESSMENT BI-RADS™ CATEGORY 5	
#5 TOTAL CASES FROM FINAL ASSESSMENT BI-RADS™ CATEGORIES 4 AND 5 THAT UNDERWENT CORE BIOPSY/FNA	
#5A NUMBER OF THESE THAT WERE MALIGNANT	
#5B NUMBER OF THESE THAT WERE BENIGN	
#6 TOTAL CASES FROM FINAL ASSESSMENT BI-RADS™ CATEGORIES 4 AND 5 THAT UNDERWENT SURGICAL BIOPSY	
#6A NUMBER OF THESE THAT WERE MALIGNANT	
#6B NUMBER OF THESE THAT WERE BENIGN	
#7 TOTAL CASES FROM FINAL ASSESSMENT BI-RADS™ CATEGORIES 4 AND 5 THAT WERE LOST TO FOLLOW-UP, REFUSED BIOPSY, OR SURGEON ELECTED TO FOLLOW RATHER THAN BIOPSY	
#8 TOTAL CANCERS FOUND THAT WERE DUCTAL CARCINOMA IN SITU	
#9 TOTAL CANCERS FOUND THAT WERE INVASIVE DUCTAL CARCINOMA OR INVASIVE LOBULAR CARCINOMA	
#10 TOTAL CANCERS FOUND THAT WERE INVASIVE DUCTAL CARCINOMA OR INVASIVE LOBULAR CARCINOMA FOR WHICH AXILLARY SAMPLING WAS PERFORMED	
#11 TOTAL NUMBER OF INVASIVE CANCERS THAT WERE ≤ 1cm IN SIZE	
#12 TOTAL NUMBER OF INVASIVE CANCERS THAT SHOWED POSITIVE AXILLARY LYMPH NODES AT SURGERY	

NOTE : BI-RADS™ CATEGORY 3 CASES ARE NOT LISTED HERE BECAUSE THEY ARE CONSIDERED NEGATIVE.

FIG. 7

# SAMPLE CALCULATION (DERIVED DATA)

BASIC CLINCIAL RELEVANT AUDIT, SCREENING CASES ONLY

FORM B

RESULT

PARAMETER TO BE CALCULATED

EQUATION\*

NUMBER OF TRUE POSITIVE (TP)	5A + #6A	
NUMBER OF FALSE POSITIVES (FP) THREE DEFINITIONS:		
FP <sub>1</sub>	#2-TP	
FP <sub>2</sub>	#5B + #6B + #7	
FP <sub>3</sub>	#5B + #6B	
POSITIVE PREDICTIVE VALUE THREE DEFINITIONS:		
PPV <sub>1</sub> (HOW OFTEN ABNORMAL SCREENS ARE CANCER)	[TP]/#2	
PPV <sub>2</sub> (HOW OFTEN BIOPSIES RECOMMENDED ARE CANCER)	[TP]/[TP + FP2]	
PPV <sub>3</sub> OR BPR (HOW OFTEN BIOPSIES DONE ARE CANCER)	[TP]/[TP + FP3]	
CANCER DETECTION RATE	([TP]/[#1]) X 1000	
PERCENT MINIMAL CANCERS (INVASIVE CANCERS ≤ 1cm, OR DUCTAL CARCINOMA IN SITU) FOUND	([#8 + #11]/[TP]) X 100	
PERCENT AXILLARY NODE-POSITIVE INVASIVE CANCER FOUND	(#12)/[#0] X 100	
% RECALL (i.e. RECALL RATE)	([#2]/[#1]) X 100	

\* NUMBER REFER TO DATA ITEMS ON FORM A



# FIG.8

## PRACTICE DATA SET FOR FORMS A AND B

PLEASE USE THE FOLLOWING HYPOTHETICAL DATA SET FOR FORM A AS A PRACTICE EXERCISE FOR PERFORMING THE REQUISITE CALCULATIONS OF FORM B FOR THE BASIC AUDIT.

1.	5000
2.	450
3.	50
4.	40
5.	43
5A.	15
5B.	28
6.	42
6A.	15
6B.	27
7.	5
8.	6
9.	24
10.	23
11.	9
12.	4

### ANSWERS TO CATEGORIES ON FORM B:

TP=30

FP<sub>1</sub>=420

FP<sub>2</sub>=60

FP<sub>3</sub>=55

PPV<sub>1</sub>=.07(7%)

PPV<sub>2</sub>=.33(33%)

PPV<sub>3</sub>=.35(35%)

CANCER DETECTION RATE=6/1000

% MINIMAL CANCERS=50%

%NODE POSITIVE INVASIVE CANCERS=17%

RECALL RATE=9%

# FIG.9

